In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

HERBERT E. BOWLING, JR., As Executor of the Estate of Evelyn L. Bowling,	*	
Petitioner,	*	No. 18-109V Special Master Christian J. Moran
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Filed: September 20, 2023
Respondent.	*	

Simina Vourlis, Columbus, OH, for petitioner;
Colleen Hartley, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT TO COMPENSATION[1]

Herbert E. Bowling, as executor of the estate of Evelyn L. Bowling, alleged that the influenza ("flu") vaccine caused Ms. Bowling to suffer transverse myelitis ("TM"), and this transverse myelitis ultimately led to her death. Pet., filed Jan. 23, 2018. The Secretary disputed this allegation, contending that transverse myelitis is not an appropriate diagnosis and that Mr. Bowling failed to prove that there is a causal link between the flu vaccination and TM. The parties developed their positions by presenting expert reports and by arguing through legal memoranda.

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

The evidence, viewed in its entirety, does not preponderate in favor of finding that the flu vaccine can cause TM. Thus, whether Ms. Bowling suffered from transverse myelitis is academic. Mr. Bowling is not entitled to compensation.

I. Facts

A. Pre-Vaccination

Ms. Bowling was born in 1937. Before her flu vaccination on October 1, 2015, Ms. Bowling saw several physicians for various medical issues. The first notable medical event was when she was admitted to the emergency room for episodes of dizziness with vomiting in early September 2014. See Exhibit 4 at 41-42. Thereafter, she frequently suffered from multiple episodes of dizziness accompanied by nausea and vomiting. She sought medical care from her primary care physician, Dr. Mark Komar, at Lake County Family Practice and an ear, nose and throat specialist, Dr. Michael Gaugler. Both physicians diagnosed her with dizziness. Id. at 41-42, 74-75.

Ms. Bowling's symptoms did not improve over the next several months. In March 2015, an MRI of the brain without contrast showed scattered foci and frontal parietal occipital white matter that was described as "nonspecific and consistent with age-related change and/or chronic white matter ischemic disease." Id. at 68. The notes documented: "No acute changes, ischemia or hemorrhage. Moderate periventricular small vessel ischemic disease." Id. at 79. Dr. Gaugler commented that the "MRI was essentially normal." Id. at 68.

At the end of April 2015, Ms. Bowling began exhibiting neurologic symptoms for which she sought treatment in an emergency room. She felt numbness in her right-hand fingers that radiated through her right forearm and right side of her mouth. See id. at 77. The emergency room physicians concluded that those symptoms were the result of hyponatremia and a urinary tract infection. Id. She had no other neurological deficits, speech impairments, vision changes, or altered level of consciousness. Id. About a week later, she went to the emergency room again for a sudden inability to express herself. Id. On April 30, 2015, the CT scan of the head was negative for acute changes. Exhibit 4 at 79.

In May 2015, Ms. Bowling had approximately two to three episodes of right-sided numbness or difficulty speaking associated with numbness and tingling in her right hand. Id. at 15. On May 6, 2015, Dr. Komar diagnosed her with 1)

transient ischemic attack ("TIA") and cerebral infarction without residual deficits, 2) unspecified transient cerebral ischemia, and 3) UTI. Id. at 27. An MRI of the brain from May 2015 revealed "mild burden of nonspecific white matter hyperintensities [that] are likely of chronic small vessel ischemic origin." Exhibit 4 at 99. An MRA of the brain and neck showed no significant vessel stenosis or compromise. Id. at 79.

In the following months, Ms. Bowling continued to suffer from neurologic symptoms. On July 6, 2015, Ms. Bowling saw Dr. Gabor Toth, a neurologist at the Cerebrovascular Center at Cleveland Clinic, for evaluation of recurrent transient neurologic events. Exhibit 4 at 77. After examining her, Dr. Toth's differential diagnoses considered the possibility of strokes versus seizures. Id. at 80. He ordered an extended EEG study. Id.

On the morning of July 23, 2015, Ms. Bowling called Dr. Toth's office to report that she was hospitalized for episodes of flashing lights with left arm and hand tingling and left facial numbness.[2] Id. at 87. Later that day, Dr. Toth reviewed her EEG results which did not show signs of a stroke but showed "slowing." Id. He prescribed Keppra 250 mg twice daily.[3]

On July 29, 2015, Ms. Bowling saw Dr. Komar, who recorded that she was seen for a follow-up appointment from a recent hospitalization.[4] Ms. Bowling informed Dr. Komar that she was "hospitalized again for an episode of persistent numbness and tingling [that] started in her [right] hand and moved up [to] her arm." Id. at 10-11. Dr. Komar wrote that she "[c]ertainly . . . had progressive neurologic [symptoms] associated with these events and it is sounding less and less like a TIA." Id. at 11. He diagnosed her with "marching paresthesias" in her right arm and recommended her to continue taking Keppra and Aspirin as well as follow up with a neurologist. Id.

The parties have not cited to any other medical records from before the vaccination.

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[2] It appears that Ms. Bowling was hospitalized from July 21, 2015 to July 22, 2015. See Exhibit 5 at 149.

[3] A medical record from July 29, 2015 indicated Dr. Toth prescribed Keppra for seizures. Exhibit 4 at 10.

[4] This hospitalization appears to be the same one that Ms. Bowling reported to Dr. Toth's office on July 23, 2015 because the July 29, 2015 notes discuss her calling Dr. Toth after discharge. Exhibit 4 at 10.

B. Vaccination and Thereafter

Ms. Bowling received a flu vaccination when she was 78 years old on October 1, 2015. Exhibit 3.

On October 8, 2015, Ms. Bowling saw Jordan Smith, PA-C at Lake County Family Practice, for a three-day history of urinary urgency and frequency. Exhibit 4 at 7. The physician assistant diagnosed her with a UTI and prescribed Ciprofloxacin to treat it. Id.

The following day, on October 9, 2015, Ms. Bowling returned to Jordan Smith for evaluation of bilateral leg weakness, which had been "occurring on a[n]d off for several months to years," but she "noticed it more frequently the last several days." Id. at 4. The physician assistant noted that there was "no official cause of her balance and unsteadiness." Id. at 5.

On October 15, 2015, Ms. Bowling presented to Lake Hospital System with numbness and tingling of her bilateral lower extremities. Exhibit 5 at 149. The next day, on October 16, 2015, a neurologist noted that Ms. Bowling had transient paresthesias in the right upper and left upper extremities three months ago. Id. at 73. The neurologist examined her, and the impression notes were: "Possible Guillain-Barre syndrome. We would like to get MRI of the remainder of the spine as well as MRI of the pelvis. We will check spinal fluid as well as sed rate, CRP, IgA level, and start her on the IVIG." Id. at 74. Her EEG report was normal. Id. at 198. Her cerebral spinal fluid ("CSF") showed an elevated protein level of 115 mg/dL. Id. at 161. Her brain MRI without intravenous contrast showed "mild age-related and chronic postischemic changes." Id. at 272. Her thoracic spine MRI revealed an enhancement at T3-T6, which according to a radiologist, was suggestive of "possible transverse myelitis versus infarct versus neoplastic process." Id. at 93. A physician recommended her to be transferred to a tertiary care facility for further evaluation, but Ms. Bowling preferred to be transferred to University Hospital. Id.

Ms. Bowling was discharged on October 19, 2015 from Lake Hospital System. Later that day, she was transferred to University Hospital with a "working [diagnosis] of transverse myelitis." Exhibit 6 at 10. Dr. Sindhu Richards, a resident, noted that the diagnosis was "most likely transverse myelitis." Id. He commented that the "temporal relationship to the flu vaccination is interesting" and prescribed large doses of Solumedrol. Id.

From then on, Ms. Bowling's health deteriorated. On October 28, 2015, she had a plasma exchange and developed an altered mental status after the second cycle. Id. at 672. A brain CT from October 31, 2015 showed numerous hemorrhagic lesions in the cerebral hemispheres bilaterally.[5] Id. at 248-49. On November 2, 2015, Ms. Bowling had a left facial droop. Id. at 274. On November 4, 2015, Ms. Bowling had another MRI that revealed multiple hemorrhagic foci without abnormal enhancement. Id. at 293-94. The next day, on November 5, 2015, a rheumatologist commented that Ms. Bowling's "probable transverse myelitis appears to be an autoimmune inflammatory process of unknown etiology, consistent with idiopathic transverse myelitis (although administration of vaccine 1 week prior to onset of symptoms may be a factor)." Id. at 616. On November 9, 2015, Ms. Bowling was transferred to Kindred Transitional Care and Rehabilitation-Lake Med with a final discharge diagnosis of transverse myelitis. Id. at 672-73; Exhibit 7 at 1.

In December 2015, Ms. Bowling was admitted to University Hospital for altered mental status. Exhibit 6 at 2659. Her EEG showed slowing over the left frontal lobe, and her brain MRI revealed multiple scattered areas of diffusion in both hemispheres. Id. at 2660. On December 21, 2015, a frontal lobe brain biopsy showed intravascular Large B-cell Lymphoma ("IVLBCL"). Id. at 2307.

On January 23, 2016, Ms. Bowling was readmitted to University Hospital for chills and weakness for two days. On January 25, 2016, Dr. Dana Mandel opined that the "symptoms [were] secondary to intravascular b-cell lymphoma and unlikely to be secondary to autoimmune vasculitis." Exhibit 6 at 4153. A PET scan on January 25, 2016 did not reveal active lymphoma. Id. at 4181. Ms. Bowling started taking dexamethasone for her IVLBCL. Id. On February 1, 2016, her family decided that she return to her assisted living facility and forgo future cancer treatment. Exhibit 6 at 4265.

Ms. Bowling's health worsened throughout the following months. She passed away on June 21, 2016; her death certificate listed the cause of death as "end stage dementia" with an onset of "years." Exhibit 11.

[5] According to petitioner's expert, Dr. Laughlin, this CT scan was the initial evidence of intravascular large B-cell lymphoma, appearing 30 days after the flu vaccine. Exhibit 44 at 9. Petitioner points out that the timing of the initial symptoms of intravascular large B-cell lymphoma is relevant because the intravascular large B-cell lymphoma symptoms occur after her diagnosis of transverse myelitis on October 19, 2015. According to petitioner, this evidence proves that transverse myelitis and intravascular large B-cell lymphoma are separate and distinct illnesses. Pet'r's Am. Br. at 12.

II. Procedural History

Mr. Bowling, as executor of the estate of Ms. Bowling, alleged that the flu vaccine caused Ms. Bowling's injuries and death. Pet., filed Jan. 23, 2018. He filed medical records and confirmed that the record was complete on February 26, 2018.

The Secretary contended that the medical evidence did not support petitioner's allegation and recommended that compensation be denied. Resp't's Rep., filed Dec. 17, 2018. Specifically, the Secretary noted that the medical personnel of the Division of Injury Compensation Programs did not believe that the "diagnosis of TM is medically sound and conversely, believe that Ms. Bowling suffered from Large B-Cell Lymphoma of the central nervous system, which was more likely than not present prior to the subject flu vaccination." Id. at 7. Furthermore, the Secretary asserted that the medical records did not support a medical theory causally linking the flu vaccine to her alleged injury. Id.

To facilitate the process of presenting expert reports, a set of instructions were proposed and then made final. Orders, issued April 25, 2019 and June 10, 2019.

Mr. Bowling filed a report from a neurologist whom he had retained, Dr. Nizar Souayah, on January 30, 2020. Dr. Souayah generally opined that the influenza vaccination caused Ms. Bowling's transverse myelitis by either molecular mimicry or non-specific activation of the immune system. Exhibit 14 at 42. From his perspective, transverse myelitis, along with its sequelae, ultimately led to her death. Id. Dr. Souayah cited a few case reports to demonstrate that individuals had transverse myelitis after receiving an influenza vaccine. Id. at 25-27. Dr. Souayah also cited case reports showing that the diagnosis of lymphoma has been associated with transverse myelitis. Id. at 27-28. Dr. Souayah pointed out that Ms. Bowling exhibited first symptoms of transverse myelitis on October 9, 2015, approximately 8 days after her vaccine, when she complained of bilateral leg weakness with unsteady gait. Id. at 35 (citing Exhibit 4 at 4-5). He maintained that there was no evidence that Ms. Bowling experienced any symptoms of primary central nervous system large B-cell lymphoma ("PCNSL") prior to her brain biopsy on December 21, 2015. Id. He asserted that the lymphoma was "likely an incidental silent finding unrelated to Ms. Bowling's transverse myelitis." Id. at 40.

The Secretary responded by submitting a report from a hematologist/oncologist whom he had retained, Dr. Kenneth McClain, on May 8, 2020 and a report from a neurologist whom he had retained, Dr. Peter Donofrio, on May 28, 2020. Exhibit A&D. Dr. McClain found Dr. Souayah's assertion that Ms. Bowling's lymphoma was an incidental finding to be unreliable, and he provided multiple reasons.[6] Exhibit A at 11. Dr. McClain disputed Dr. Souayah's assertions that there were no symptoms of the primary central nervous system large B-cell lymphoma prior to her brain biopsy on December 21, 2015. Dr. McClain maintained that her mental status changes and dementia were early signs of the PCNSL,[7] an intravascular B-cell lymphoma, which was the cause of her symptoms and death. Id. at 10. Dr. McClain stated that there are no reported cases of systemic or primary central nervous system lymphoma following vaccination and "it is not generally accepted in the oncology medical community that the flu vaccine can cause intravascular large B-cell lymphoma." Id.

The Secretary's second expert, Dr. Donofrio, challenged the diagnosis of transverse myelitis because Ms. Bowling did not meet the full criteria for the condition:

> [S]he had a neoplastic cause for her spinal cord lesion, the intravascular Large B-Cell Lymphoma, which would exclude the diagnosis. In addition, she did not recover[] within 3 months of the onset of her paraplegia which is not typical for idiopathic TM. The decedent is also much older than the bimodal peak for TM of 10 to 19 and 30 to 39 years.

Exhibit D at 7. According to Dr. Donofrio, Ms. Bowling did not have TM, so TM could not have caused her injuries and death. Id. Dr. Donofrio further rebutted

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[6] Dr. McClain commented: "The fact that extensive neurologic testing and brain imaging done between March 2015 and May 2015 was negative only points to the fact that the onset of lymphoma was some time after those dates or that the extent of the malignancy was below the detection limits of CT and MRI scans." Exhibit A at 11. Dr. McClain discussed two case reports, found in the N. Kumar et al., Intravascular lymphoma presenting as longitudinally-extensive myelitis: diagnostic challenges and etiologic clues, 303 J. NEUROL SCI. 146 (2011) and A. Ormsby et al., Angiotrophic large cell lymphoma mimicking multiple sclerosis associated transverse myelitis, 5 J. CLIN NEUROSCI 408 (1999), of intravascular lymphoma of the spinal cord mimicking transverse myelitis, so "there is precedent for the proposed TM in Ms. Bowling actually being the intravascular lymphoma." Id. at 12.

[7] Petitioner's expert, Dr. Laughlin, points out that Dr. McClain confuses IVLBCL with PCNSL. According to Dr. Laughlin, IVLBCL and PCNSL are different. Exhibit 44 at 8.

that the flu vaccine can cause TM because "there are very few case reports of TM developing after the flu vaccine and no epidemiologic studies showing a causal relationship." Id. Dr. Donofrio proposed that intravascular large B-cell lymphoma was the likely diagnosis to explain Ms. Bowling's symptoms. He commented that this type of lymphoma can be "slow growing" and can affect different locations in the central nervous system, explaining her episodes of numbness and tingling, dizziness and vertigo, aphasia, vision loss, and flashing lights, as all those symptoms and signs can be localized to the brain and brainstem. Id. at 9. He cited to Dennis Orwat & Nicholas Batalis, Intravascular large B-cell lymphoma, 136 ARCH PATHOL LAB MED 333 (2012) to support his proposition.[8]

On June 12, 2020, a status conference was held to discuss Dr. McClain's and Dr. Donofrio's reports, particularly regarding Dr. McClain's diagnosis of large B cell lymphoma and Dr. Donofrio's disagreement of Ms. Bowling's alleged diagnosis of transverse myelitis. Mr. Bowling expressed an interest to file a responsive report from Dr. Souayah and to retain an oncologist to provide a report. Order, issued June 12, 2020.

On September 14, 2020, Mr. Bowling filed an expert report from Dr. Laughlin (Exhibit 44) and a supplemental expert report from Dr. Souayah (Exhibit 53). Dr. Laughlin stated that Dr. Donofrio mistakenly confused intravascular large B-cell lymphoma with primary CNS lymphoma since the two are "in no manner similar." Exhibit 44 at 8. Therefore, primary CNS lymphoma is completely irrelevant in Ms. Bowling's case. Dr. Laughlin emphasized that clinical evidence supports that Ms. Bowling developed both IVLBCL and TM, and both contributed to her death. Dr. Laughlin asserted that Dr. Donofrio's opinion that IVLBCL is "slow growing" is "significantly flawed because [IVLBCL] is very aggressive with rapid onset." Exhibit 44 at 9. Dr. Souayah's supplemental expert report agreed with Dr. Laughlin's report. Exhibit 53.

On November 23, 2020, the Secretary filed supplemental expert reports from Dr. Donofrio and Dr. McClain. Exhibit G&H. Dr. Donofrio maintained that IVLBCL was the diagnosis that best explained Ms. Bowling's symptoms dating

[8] The Orwat article actually states that intravascular large B-cell lymphoma is "aggressive, and without treatment is rapidly fatal." Exhibit D-2 at 333. Petitioner's expert, Dr. Laughlin, pointed out Dr. Donofrio's misstatement, too. In a supplemental expert report, filed on November 23, 2020, Dr. Donofrio agreed that IVLBCL is an aggressive form of lymphoma when left untreated: "When one considers the onset of her myelopathy in mid-October 2015 and her death in June 2016, the rate of progression would be considered an aggressive form of neoplasm." Exhibit G at 1.

back to 2014. Exhibit G at 4. Dr. McClain, on the other hand, acknowledged that he was imprecise when describing primary CNS lymphoma. He clarified: "What I intended to communicate was that the lymphoma affecting this patient was fundamentally or principally (two alternative words for "primary" as listed in Roget's Thesaurus) affecting her brain." Exhibit H at 1.

Both parties continued to submit supplemental expert reports in January 2021 and February 2021. See Exhibits 54, I, and J. Once the expert report phase concluded, the undersigned held a status conference on March 3, 2021 to encourage the parties to consider settlement and directed respondent to file a status report to advise on his litigation position. Order, issued Mar. 3, 2021. The Secretary reported that he was interested in defending the case. Resp't's Status Rep., filed Apr. 19, 2021. The parties were, accordingly, directed to advocate for their positions in written submissions. Order, issued April 28, 2021.

On September 30, 2021, Mr. Bowling submitted his brief. The undersigned found that the brief was inadequate because it did not specify the theories by which the flu vaccine can cause transverse myelitis. Also, the brief did not discuss all the medical literature filed along with the petitioner's expert reports, suggesting that the medical literature is unimportant. Therefore, a status conference was held on October 22, 2023 to address these matters. Orders, issued Oct. 14, 2021 and Oct. 22, 2021.

On November 5, 2021, Mr. Bowling filed his amended brief. Mr. Bowling wrote:

> [A]n oral hearing will not have any bearing on the Special Master's ability to decide this case [as] [t]he affidavit, medical records, pleadings and expert reports are complete and extensive. It is unlikely that a ruling on the record will be any different from a ruling made after hearing oral testimony.

Pet'r's Am. Br. at 40. On March 17, 2022, the Secretary submitted his brief. With the filing of Mr. Bowling's reply brief on May 26, 2022, the case is ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more

probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

When pursuing an off-Table injury, a petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IV. Analysis

A. Diagnosis

While establishing a diagnosis is also required, see Broekelschen v. Sec'y of Health and Human Servs., 618 F.3d 1339 (Fed. Cir. 2010), the undersigned does not make a finding on diagnosis for the reasons that follow. The Secretary disputed Ms. Bowling's transverse myelitis diagnosis. Dr. Donofrio listed the diagnostic criteria for transverse myelitis from the manuscript by Frohman and Wingerchuk.[9] He explained that Ms. Bowling did not meet the full criteria because she had a neoplastic cause for her spinal cord lesion, the intravascular Large B-Cell Lymphoma, excluding a transverse myelitis diagnosis. Exhibit D at 7. Additionally, she did not recover within 3 months of the onset of her paraplegia which is not typical for idiopathic TM. Id. Ms. Bowling is also much older than the bimodal peak for TM of 10 to 19 and 30 to 39 years. Id.

[9] Elliot M. Frohman & Dean M. Wingerchuk, Clinical Practice. Transverse Myelitis, 363 N. ENGL. J. MED. 564 (2010); filed as Exhibit D-1.

Mr. Bowling maintained that Ms. Bowling had a definitive diagnosis of TM. In addition to meeting all diagnostic criteria for TM, medical records indicate that she had a diagnosis of TM. Pet'r's Am. Br. at 23 (citing Exhibit 6 at 9). Mr. Bowling also pointed out that "a neoplastic process was considered less likely due to lack of findings on Ms. Bowling's October 16, 2015, brain MRI." Pet'r's Am. Br. at 23 (citing Exhibit 5 at 261).

The Secretary attributed Ms. Bowling's symptoms to IVLBCL because it explains her multiple episodes of numbness and tingling, dizziness and vertigo, aphasia, vision loss, and flashing lights. Exhibit D at 9. It is undisputed that she was diagnosed with IVLBCL on December 21, 2015. Exhibit 6 at 2307; Resp't's Br. at 23. However, it remains unclear when she actually developed IVLBCL. Was the onset of IVLBCL before or after the flu vaccine? If the onset was after the flu vaccine, at which point in time did she start having it? The parties essentially disagree on this timeframe. Dr. McClain opined that the neurologic symptoms that were evaluated in March 2015 were early signs of PCNSL. Mr. Bowling, on the other hand, argued in his brief that an onset in March 2015 was unlikely because "[g]iven that IVLBCL is a very aggressive cancer with very rapid onset and progression to death in the absence of treatment, if Ms. Bowling had IVLBCL in March 2015, it would have manifested and progressed very rapidly to death well before October 2015." Pet'r's Am. Br. at 13 (citing Exhibit D-2); see also Pet'r's Reply at 8-9.

Dr. Laughlin opined that Ms. Bowling developed both IVLBCL and TM, which concurrently contributed to her death.[10] Exhibit 44 at 9. Dr. McClain and Dr. Donofrio ruled out TM as a diagnosis; they asserted that IVLBCL was the single valid diagnosis.

Based on the medical records, literature, and briefs, it is not entirely clear if Ms. Bowling developed TM. However, at this time, it is not necessary to determine diagnosis because this case can be resolved without determining a diagnosis. For the sake of evaluating the Althen prongs, Mr. Bowling is assumed to have established that Ms. Bowling suffered from TM.

[10] Mr. Bowling is not claiming that the flu vaccine caused Ms. Bowling's lymphoma. Rather, he emphasizes that IVLBCL developed after Ms. Bowling contracted TM. Pet'r's Am. Br. at 24.

B. Althen Prong One

As part of his burden to establish that the flu vaccine was the cause-in-fact of Ms. Bowling's (assumed) transverse myelitis, Mr. Bowling must present "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. The parties have presented different forms of evidence on this topic, including (1) an epidemiologic study, (2) a post-marketing report (3) case reports and case series, and (4) opinions from experts regarding specific theories. These are discussed below.

1. Epidemiology

For a lengthy discussion of the value of epidemiologic studies in the Vaccine Program, see Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *5-8 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448, 475 (2020); see also P.M. v. Sec'y of Health & Hum. Servs., No. 16-949V, 2019 WL 5608859, at *24-25 (Fed. Cl. Spec. Mstr. Sep. 24, 2019) (finding that epidemiologic studies weighed against finding the flu vaccine can worsen multiple sclerosis); King v. Sec'y of Health & Hum. Servs., No. 03-584V, 2010 WL 892296, at *74 (Fed. Cl. Mar. 12, 2010) ("special masters have routinely found that epidemiologic evidence, and/or other medical journal articles, while not *dispositive,* should be *considered* in evaluating scientific theories").

To contest Dr. Souayah's contention that a flu vaccine can cause transverse myelitis, respondent pointed out that "even Dr. Souayah submitted a paper regarding a large-scale study, published in 2016 [Baxter], following 64 million vaccine doses that significantly found no causal association between vaccinations and TM." Resp't's Br. at 17.

The Baxter study evaluated all administered vaccines from January 2007 to December 2012, both individually and combined, and to increase the power of the study, combined all inactivated influenza vaccines together, including trivalent, quadrivalent, and high dose. Exhibit 40 (Roger Baxter et al., Acute Demyelinating Events Followng Vaccines: A Case-Centered Analysis, 63 CLIN INFECT DIS. 1456 (2012)) at 3. Only 7 cases of TM were detected during the primary exposure window of 5-28 days following administration of nearly 64 million vaccine doses. Id. at 1. The researchers found no increase in TM frequency within the vaccine exposure interval of 5-28 days or within the timeframe of 2-42 days. Id. The 2-42 day interval was used because the researchers wanted to ensure they were "not

missing an increased risk with the same type of vaccine, beyond the shorter 5-28 day exposure interval." Id.

Mr. Bowling argued that epidemiological studies, such as Baxter, are flawed and "may not detect or rule out rare events." Pet'r's Am. Brief at 30 (citing Exhibit 36 (Institute of Medicine, Adverse Effects of Vaccines Evidence and Causality, Stratton, Kathleen et al. (eds) (2012) at ix-x)). Mr. Bowling attempted to undermine the Baxter study, for instance, because it had flaws: 1) it is a retrospective study using diagnostic codes, 2) the study involves 64 million vaccinations, not 64 million patients, and 3) the study used a shorter risk period than the Schonberg study which was the first controlled study that demonstrated the significant increase of GBS after swine flu vaccination. Id. at 31.

While the Baxter study is not dispositive, it does lend support to vaccines not being a known cause of TM. See Martinez v. Sec'y of Health & Hum. Servs., No. 16-738V, 2022 WL 4884923, at *30 (Fed. Cl. Spec. Mstr. Sept. 9, 2022) (recognizing that Baxter "contains some methodologic weaknesses . . . [b]ut still undermines petitioners' theory- especially given the degree to which petitioners relied on case reports in the alternative"), mot. for rev. denied, 165 Fed. Cl. 76 (2023); Bender v. Sec'y of Health & Hum. Servs., No. 11-693V, 2018 WL 3679637, at *30 (Fed. Cl. Spec. Mstr. July 2, 2018), mot. for rev. denied, 141 Fed. Cl. 262, 268 (2019), but see J. v. Sec'y of Health & Hum. Servs., 155 Fed. Cl. 20, 47 (2021).

2. Post-Marketing Surveillance

Mr. Bowling asserted that post marketing surveillance was a more reliable method to detect rare adverse effects, pointing out that "post marketing surveillance led [] directly to the manufacturer of Fluzone High Dose 2015-2016 listing TM as an adverse reaction during post-approval use of the vaccination." Pet'r's Am. Br. at 32 (citing to Section 6.2 Post-Marketing Experience in Exhibit 55 at 3). He stated that Fluzone High Dose was the "exact vaccination Mrs. Bowling received." Id. at 32 (citing Exhibit 3).

Mr. Bowling takes words out of context. The section of the package insert that provides information about the "Post-Marketing Experience" limits the usefulness of the information. It starts: "The following events have been spontaneously reported during the post-approval use of Fluzone or Fluzone High-Dose. Because these events are reported voluntarily from a population of uncertain size, it is *not always possible to reliably estimate their frequency or establish a*

causal relationship to vaccine exposure." Exhibit 55 at 3 (emphasis added). Furthermore, although Mr. Bowling states that section 6.2 presents "adverse reactions," the package insert uses the more innocuous term "Adverse events." Mr. Bowling's reliance on the post marketing surveillance is unpersuasive since "[s]tatements contained in vaccine package inserts do not constitute reliable proof of causation, and cannot be deemed admissions that the vaccines in question have the capacity to harm a particular petitioner in a specific manner." Sullivan v. Health and Hum. Servs., No. 10-398V, 2015 WL 1404957 at *20 (Fed. Cl. Spec. Mstr. Feb. 13, 2015). For a description of how package inserts are prepared, see Cottingham v. Sec'y of Health & Hum. Servs., No. 15-1291, 2021 WL 6881248, at *29-33 (Fed. Cl. Spec. Mstr. Sep. 27, 2021), mot. for rev. denied, 159 Fed. Cl. 328 (2022), appeal docketed, No. 2022-1737 (Fed. Cir. Apr. 28, 2022).

3. Case Reports

Without any epidemiologic evidence that directly connects the flu vaccine with Ms. Bowling's TM, Mr. Bowling relies upon case reports about a flu vaccine preceding the onset of TM to support the claim that a flu vaccine can cause TM. See Pet'r's Am. Br. at 26 and Pet'r's Reply at 11. This position is flawed because case reports provide little, if any, meaningful information about causation. At best, they show temporal data but not necessarily that a flu vaccine can cause TM.

Various authorities have commented on the value of case reports. To start, the Federal Judicial Center has published a series of guides designed "to assist judges . . . in reaching an informed and reasoned assessment concerning the basis of expert evidence." Jerome P. Kassirer and Gladys Kessler, Reference Manual on Scientific Evidence, Preface (3d ed. 2011) ("Reference Manual"). The guidance from the Federal Judicial Center translates to the Vaccine Program because causation for off-Table injuries in the Vaccine Program is the same as traditional causation. See Moberly, 592 F.3d at 1322-23; Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999) ("The absence of elaboration of the law of causation in the legislative history leads us to conclude that the Vaccine Act's requirement of causation in non-Table cases was not viewed as distinct from causation in the tort law."). For examples in which appellate authorities within the Vaccine Program have cited the Reference Manual, see Germaine v. Sec'y of Health & Hum. Servs., 155 Fed. Cl. 226, 228-29 (2021), and Hart v. Sec'y of Health & Hum. Servs., 60 Fed. Cl. 598, 607 n.20 (2004).

A pertinent guide in the Reference Manual states "[a]necdotal evidence usually amounts to reports that events of one kind are followed by events of

another kind. Typically, the reports are not even sufficient to show association, because there is no comparison group." David H. Kaye and David A. Freedman, Reference Manual on Scientific Evidence, Reference Guide on Statistics, at 218. These authors also state "some courts have suggested that attempts to infer causation from anecdotal reports are inadmissible as unsound methodology under Daubert." Id. at 217 n. 14 (citing cases).

Within the Vaccine Program, the Federal Circuit has endorsed, albeit indirectly, a view that case reports merit little weight. In a series of five cases involving auto-immune hepatitis, the (undersigned) special master rejected case reports as evidence of causation. Porter v. Sec'y of Health & Hum. Servs., No. 99–639V, 2008 WL 4483740, at *13 (Fed. Cl. Spec. Mstr. Oct. 2, 2008). Under the caption of a different case, a judge at the Court of Federal Claims disagreed with this weighing of evidence. Rotoli v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 71, 86–87 (2009). When the Federal Circuit reviewed the special master's decision, the Federal Circuit stated that "[t]he special master found that the remaining two articles, both describing single case studies, did not contain any meaningful analysis about causation." Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1253 (Fed. Cir. 2012). The Federal Circuit also stated that the "decision reveals a thorough and careful evaluation of all the evidence including . . . medical literature." Id. at 1254.

Similar indirect support from the Federal Circuit is found in W.C. W.C. v. Sec'y of Health & Hum. Servs., No. 07-456V, 2011 WL 4537877, at *13 (Fed. Cl. Spec. Mstr. Feb. 22, 2011), mot. for rev. denied on this point, 100 Fed. Cl. 440, 456 (2011), aff'd, 704 F.3d 1352 (Fed. Cir. 2013). At the trial level, the (undersigned) special master declined to rely upon case reports because, among other reasons, "case reports cannot distinguish a temporal association from a causal relationship." Id. at *13. At the Federal Circuit, the appellate court focused primarily upon epidemiologic studies, which undermined the claim that the vaccine significantly aggravated the petitioner's illness. W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1360-61 (Fed. Cir. 2013). However, at the end of its opinion, the Federal Circuit stated that it "cannot say that the special master's . . . weighing of the scientific evidence was arbitrary or capricious." Id. at 1361.

Much of the foregoing analysis regarding case reports was set forth in K.O. v. Sec'y of Health & Human Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016). After K.O., the Federal Circuit has not discussed case reports in a precedential opinion, leaving Porter and W.C. as the leading, although muted, words on the subject. Consequently, judges from the

Court of Federal Claims have tended to defer to the special master's assessment of case reports. See, e.g., Kelly v. Sec'y of Health & Hum. Servs., 160 Fed. Cl. 316, 319 (2022) (indicating that the special master was not arbitrary in finding that case reports have limited or nonexistent value); Rus v. Sec'y of Health & Hum. Servs., 129 Fed. Cl. 672, 682 (2016) (noting the special master could reasonably afford little weight to the medical literature, including case reports). An exception to this trend is Patton v. Sec'y of Health & Hum. Servs., 157 Fed. Cl. 159 (2021). In Patton, the Court ruled that the special master "erred in his prong one analysis by discounting the evidentiary value of the case reports [petitioner's expert] submitted." Id. at 168. But, Patton does not discuss Porter or W.C. Instead, Patton relies upon Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 475 (2012).[11]

Outside of the Vaccine Program, district courts have examined the value of case reports in the context of claims that drugs or a medical device harmed a person. Recent examples include: In re: Abilify (Aripriprazole) Products Liability Litigation, 299 F.Supp.3d 1291, 1309 (N.D. Fla. 2018) ("The difficulty with case reports is distinguishing between association and causation"); In re Tylenol (Acetaminophen) Marketing, Sales Practice, and Products Liability Litigation, 198 F.Supp.3d 446, 461 (E.D. Pa. 2016) ("It is true that case reports and anecdotal evidence alone may not be sufficient support for a causation opinion. . . . However, case reports considered in conjunction with other evidence may be an appropriate basis for an expert's causation opinion."); In re Mirena IUD Products Liability Litigation, 169 F.Supp.3d 396, 451 (S.D.N.Y. 2016) ("Case reports are generally disfavored by courts as evidence of causation because they merely describe 'reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; [they] do not isolate and exclude potentially alternative causes; and [they] do not investigate or explain the mechanism of causation.'") (citation omitted).

[11] Paluck states "case reports 'do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value. Nonetheless, the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight.'" Paluck, 104 Fed. Cl. at 475, quoting Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011). The case Paluck quotes, Campbell, cites to Rotoli v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 71, 86-87 (2009). However, the value of the opinion by the Court of Federal Claims seems questionable as the Federal Circuit, as noted above, reversed the outcome in Rotoli, and reinstated the special master's decision, which gave little weight to the case reports. Porter, 663 F.3d at 1253. Paluck, which cited Rotoli, was issued before the Federal Circuit reversed Rotoli.

Mr. Bowling discussed case reports showing development of TM after the flu vaccination. See Pet'r's Am. Br. at 38. As these case reports are part of the record, they must be considered.[12] See 42 U.S.C. § 300aa–13(a)(1) (requiring a special master to evaluate the "record as a whole"). Mr. Bowling included the following case reports: "In the Akhad article (Ex 18), the time period between the flu vaccination and the development of TM was four days. The Wu article (Ex 19) notes a period of two weeks between flu vaccination and the development of TM. The Nakamura article (Ex 20) cites 5 days. Baskshi (Ex 21) noted symptoms of TM in a patient four weeks after a routine flu shot. Korn-Lubezki (Ex 22) also noted one month. The Sato (Ex 23) case report notes a case of a person who developed TM one month following a trivalent flu vaccine and one day following a H1N1 vaccination." Pet'r's Am. Br. at 38. These case reports do not meaningfully demonstrate that the flu vaccine can cause transverse myelitis. See Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996) (indicating that special masters have discretion in how they weigh evidence).

In sum, the epidemiologic study tends to weigh against finding that a flu vaccine can cause TM and the case reports contribute little, if anything, to the causation analysis. However, this literature is not dispositive of the issue. Therefore, the theories Mr. Bowling and his expert have put forward are addressed next.

4. Althen Prong 1 - Individual Theories

Mr. Bowling and his expert, Dr. Souayah, advance the theories of molecular mimicry and nonspecific activation of the immune system to explain how the flu vaccination could cause TM. Exhibit 14 at 30. The Secretary disputes the persuasiveness of those theories.

a) Molecular Mimicry

Because special masters are often called upon to evaluate the persuasiveness of the theory of molecular mimicry, the Court of Federal Claims and the Court of Appeals for the Federal Circuit have considered molecular mimicry in their appellate role opinions from special masters. In December 2019, the undersigned identified the leading precedents as W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013), and Caves v. Sec'y of Dep't. of Health & Hum. Servs., 100 Fed. Cl. 119 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012).

[12] Dr. Souayah refers to other case reports in his expert report; however, this decision will focus on the case reports that Mr. Bowling advances in his brief.

Tullio v. Sec'y of Health & Hum. Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). While Tullio describes those cases in more detail, their essence appears to be that although molecular mimicry is accepted in some contexts, special masters may properly require some empirical evidence to show that a particular vaccine can cause a particular disease.

In the next approximately three years, appellate authorities reviewing decisions involving molecular mimicry have generally endorsed the approach of looking for some evidence that persuasively shows that a portion of a vaccine resembles a portion of human tissue, which contributes to causing the disease, and that the immune system will respond to the relevant amino acid sequence.[13] Chronologically, the list of more recent appellate cases begins with the opinion in Tullio, which denied the motion for review. 149 Fed. Cl. 448, 467-68 (2020).

Another example in which the Court of Federal Claims held that the special master did not elevate the petitioner's burden of proof in the context of evaluating the theory of molecular mimicry is Morgan v. Sec'y of Health & Hum. Servs., 148 Fed. Cl. 454, 476-77 (2020), aff'd in non-precedential opinion, 850 F. App'x 775 (Fed. Cir. 2021). In Morgan, the Chief Special Master found that petitioner had not presented persuasive evidence about a relevant antibody. Id. at 477. The Chief Special Master also noted that the articles about the relevant disease do not list the wild flu virus as potentially causing the disease. Id. When examining this analysis, the Court of Federal Claims concluded: "the Chief Special Master did not raise the burden of causation in this case; petitioner simply failed to meet it." Id.

The Federal Circuit also evaluated the Chief Special Master's approach in Morgan. The Federal Circuit concluded: "We discern no error in the special master's causation analysis." 850 F. App'x 775, 784 (Fed. Cir. 2021).

Most other recent appellate cases follow this path. See, e.g., Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (finding the special master did not err in rejecting a bare assertion of molecular mimicry); Caredio v. Sec'y of Health & Hum. Servs., No. 17-79V, 2021 WL 6058835, at *11 (Fed. Cl. Dec. 3, 2021) (indicating that a special master did not err in requiring more than homology and citing Tullio); Yalacki v. Sec'y of Health & Hum. Servs., 146 Fed.

[13] The term "homology" is used when discussing molecular mimicry. "Homology" is defined as "the quality of being homologous; the morphological identity of corresponding parts; structural similarity due to descent from a common form." *Dorland's* at 868.

Cl. 80, 91-92 (2019) (ruling that special master did not err in looking for reliable evidence to support molecular mimicry as a theory); but see Patton, 157 Fed. Cl. at 169 (finding that a special master erred in requiring petitioner submit a study to establish medical theory causally connecting flu vaccine to brachial neuritis).

Based upon this method of analysis, the evidence Mr. Bowling presents falls short of his burden. In Dr. Souayah's view, since Ms. Bowling had no previous history of infection including influenza prior to vaccination, the "influenza vaccination induced activation of her immune system." Exhibit 14 at 29. Dr. Souayah commented:

> Some of the antibodies produced by Mrs. Bowling's immune system against the flu vaccine, more probably than not, reacted with the myelin sheath of her peripheral nervous system and caused nerve damage. This reaction occurred because of the antigenic similarity between the vaccine, or one of its components, with the myelin sheath (molecular mimicry). The concept of molecular mimicry occurs when epitopes of a live or attenuated vaccine initiates the development of antibodies and/or T cells that can cross-react with epitopes on myelin or axonal component of a nerve.
>
> For molecular mimicry, the immune system would recognize that the vaccine and Mrs. Bowling share nearly identical antigens, which induces an antibody and T cell immune response that is cross reactive.

Id. at 29-30. Dr. Souayah's discussion of the theory of molecular mimicry is sparse and conclusory. He does not present a persuasive reason for linking Ms. Bowling's TM to the flu vaccine. His opinion is speculative because he assumes that the mere fact of the symptoms appearing after the flu vaccine means that the flu vaccine caused the symptoms. See Morgan, 850 F. App'x at 784; see also Duncan, 153 Fed. Cl. at 661. Mr. Bowling's brief is similarly conclusory on this topic. See Pet'r's Am. Br. at 27-28.

b) Nonspecific Activation of the Immune System

In explaining nonspecific activation of the immune system, Mr. Bowling copied and pasted Dr. Souayah's discussion in his expert report into his brief:

> Alternatively, a nonspecific activation of the immune system by the influenza vaccine or one of the vaccine-associated components against

> the central nervous system myelin is another well described mechanism of nerve damage. The contribution of the genetic profile and other biological factors specific to Mrs. Bowling's immune system likely predisposed her to develop transverse myelitis after vaccination.
>
> Infectious agents may induce autoimmunity via polyclonal activation of B lymphocytes or bystander activation which enhances cytokine production and further induce the expansion of auto-reactive T-cells. The latter mechanism may be associated[14] with post-infectious TM as IL-6 levels were found to be markedly elevated in the CSF of TM patients. In addition to the infectious antigen, vaccines contain several ingredients, such as adjuvants and preservatives that may contribute to triggering autoimmunity.

Exhibit 14 at 29; see also Pet'r's Am. Br. at 28-29. Mr. Bowling concluded that the "associations of different [vaccines] with a single autoimmune disease suggests that a common denominator such as an adjuvant may trigger non-specific activation of the immune system." Pet'r's Am. Br. at 29.

Mr. Bowling does not persuasively explain how the nonspecific activation of the immune system links Ms. Bowling's TM to the flu vaccination. Mr. Bowling stated that "[t]he associations of different [vaccines] with a single autoimmune disease suggests that a common denominator such as an adjuvant may trigger non-specific activation of the immune system." Id. at 29. To support his position, he cited to N. Agmon-Levin et al., Transverse myelitis and vaccines: a multi-analysis, 18 LUPUS 1198 (2009) and Wafa Akkad, MD et al., Longitudinally Extensive Transverse Myelitis Following Vaccination With Nasal Attenuated Novel Influenza A (H1N1) Vaccine, 67 ARCH NEUROL 1018 (2010). However, he does not discuss further on how these articles apply to Ms. Bowling's case. Mr. Bowling and Dr. Souayah are conclusory on this theory.

[14] Dr. Souayah wrote the "latter mechanism may be associated with post-infectious TM as IL-6 levels were found to be markedly elevated in the CSF of TM patients," which refers to "*bystander activation*." Exhibit 14 at 29. Mr. Bowling's counsel wrote "*polyclonal activation* may be associated with post-infectious TM as IL-6 levels were found to be markedly elevated in the CSF of TM patient." Pet'r's Am. Br. at 29.

The Agmon-Levin et al. article lists molecular mimicry, epitope spreading, and infectious agents as the various mechanisms by which an infectious antigen may induce autoimmunity. Exhibit 16 at 4. The researchers asserted:

> Infectious agents may induce autoimmunity via polyclonal activation of B lymphocytes or bystander activation which enhances cytokine production and further induce the expansion of auto reactive T-cells. The latter mechanism may be associated with post-infectious TM as IL-6 levels were found to be markedly elevated in the CSF of TM patients. In addition to the infectious antigen, vaccines contain several ingredients, such as adjuvants and preservatives. Adjuvants . . . are simultaneously administered with vaccines in order to induce a more vigorous immune response to the vaccinated antigens. The mechanisms of adjuvancy are not fully elucidated, however, it seems that adjuvants mimic specific sets of conserved molecules such as bacterial lipopolysaccharides . . . that activate the innate immune response. Furthermore, adjuvants protect the infectious antigen and may induce an adaptive immune response.

Exhibit 16 at 4-5. The Agmon-Levin article does little to enhance the value of petitioner's case because Agmon-Levin is essentially a case series. See I.J. v. Sec'y of Health & Hum. Servs., No. 16-864V, 2022 WL 277555, at *5 (Fed. Cl. Spec. Mstr. Jan. 4, 2022).

The Akkad et al. article discussed the Agmon-Levin et al. study that found a total of 37 cases of vaccine-associated TM. Exhibit 18 at 2. Akkad and others stated:

> While a pathogenic causal relationship has been established only for the oral poliovirus vaccine, the temporal relationship of TM with such a wide variety of vaccines suggested to those investigators that a common denominator such as an adjuvant might trigger the syndrome. The 2009 novel influenza A(H1N1) vaccines, however, do not contain an adjuvant. If a common factor between vaccines is the proximal cause of postvaccination TM, it is something other than the adjuvant in this case. Further studies of postvaccination TM, likely in model systems owing to the condition's rarity, are needed to clarify the risk and its mechanism.

Id. at 2. The Akkad authors recognize that a causal relationship between the flu vaccine and transverse myelitis has not been established and recommend further studies.

When petitioners present bystander activation in a conclusory manner, special masters may decline to endorse that theory. See Temes v. Sec'y of Health & Hum. Servs., 151 Fed. Cl. 448, 461-62 (2020), Shapiro v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 353, 359 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013). Similarly, when petitioners discuss polyclonal activation in a general sense and do not apply the theory to the specific facts in the case, special masters may discredit that theory. See Shapiro, 105 Fed. Cl. at 359 (2012); see also Smilo v. Sec'y of Health & Hum. Servs., No. 18-1585V, 2023 WL 3918397 (Fed. Cl. Spec. Mstr. May 15, 2023).

Dr. Souayah proposes molecular mimicry and non-specific activation of the immune system with minimal persuasive evidence to make those theories reliable in the context of the flu vaccine as potentially causing Ms. Bowling's TM. Case reports, strictly speaking, do not persuasively demonstrate that the flu vaccine can cause TM. Under these circumstances, Mr. Bowling has failed to meet his burden regarding Althen prong one.

Because Mr. Bowling's case is resolved based upon the first Althen prong, further evaluation of the remaining prongs is not necessary. When special masters can resolve a case a based upon one issue, they do not necessarily need to address all issues. See, e.g., Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012); Holmes v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 469, 488 (2014); Vaughan v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 212, 222 (2012). However, if Mr. Bowling had presented a persuasive theory causally connecting the flu vaccine and TM in Althen Prong 1 and continuing to assume that Mr. Bowling had presented persuasive evidence that Ms. Bowling suffered from TM, Mr. Bowling cannot establish a logical sequence of cause and effect in Althen Prong 2. A discussion of Althen Prong 2 follows.

C. Althen Prong 2- Logical Sequence of Cause and Effect

In determining whether petitioners have established that a vaccine did cause a particular injury, the Federal Circuit has directed special masters to consider any statements from treating doctors. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Mr. Bowling discussed several physicians recognizing a temporal sequence in that the flu vaccination preceded Ms. Bowling's onset of TM. See, e.g., Pet'r's Am. Br. at 34 (citing to Dr. Richards' comment that "the temporal relationship to

the flu shot is interesting" in Exhibit 6 at 10). Mr. Bowling also mentioned other doctors commenting that the administration of the flu vaccine may be a factor in Ms. Bowling's TM. Pet'r's Am. Br. at 34. These statements only indicate that Ms. Bowling's symptoms occurred shortly after receiving the flu vaccine; they do not explicitly attribute Ms. Bowling's TM to the flu vaccine. Cases distinguish between statements from treating doctors about causation from statements from treating doctors presenting sequences of events. See Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1348 (Fed. Cir. 2010) (holding that the "Special Master did not err in failing to afford significant weight to the opinions of [petitioner's] treating physicians . . . [who] simply indicat[ed] an awareness of a temporal, not causal relationship" between the symptoms and vaccine); see also Andreu v. Sec'y of Dep't of Health & Hum. Servs., 569 F.3d 1367, 1376 (Fed. Cir. 2009) (discussing that a treating physician "unequivocally" believed the vaccine caused petitioner's seizures). The medical records Mr. Bowling has identified, which present sequences of events, do not carry her burden regarding Althen prong two.

Furthermore, Mr. Bowling relied on repeated notations of Ms. Bowling's allergic reaction to flu vaccines to support his claim that the flu vaccine caused her TM. Pet'r's. Am. Br. at 35. Based upon a review of the medical records, it is unclear whether Ms. Bowling herself had reported this information to the doctors or whether the physicians made a medical determination that she was indeed allergic to flu vaccines. When patients self-report an allergy to a vaccine, special masters have declined to view that report as reflecting an independent determination of a medical professional. See Solak v. Sec'y of Health & Hum. Servs., No. 14-869V, 2020 WL 9173158, at *33 (Fed. Cl. Spec. Mstr. Feb. 19, 2020) (noting that a treating doctor apparently wrote a "letter on the history of prior reaction that Petitioner provided to him. . . I do not find it to be compelling evidence that Petitioner had an adverse reaction to her prior flu vaccines"); Pearson v. Sec'y of Health & Hum. Servs., No. 17-489V, 2019 WL 1150044, at *1 (Fed. Cl. Spec. Mstr. Feb. 7, 2019) (the "substantiation for some of these preexisting allergies comes from records in which [petitioner] provided medical histories to treaters, rather than from independent medical confirmation").

For these reasons, the affirmative evidence offered in support of a finding of a logical sequence of cause and effect between the flu vaccination and Ms. Bowling's (presumed) transverse myelitis lacks persuasive value. A lack of persuasive evidence on this point is further undermined by the presence of a potential alternative cause.

As part of determining whether the flu vaccine did cause Ms. Bowling's TM, one potential factor to consider is the presence of alternative causes. See Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1380 (Fed. Cir. 2012); Doe 11 v. Sec'y of Health & Hum. Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010). The Secretary has contended that Ms. Bowling's urinary tract infections could have caused Ms. Bowling's TM. See Exhibit G at 2; Resp't's Br. at 22, 24. Mr. Bowling contested. Pet'r's Reply at 4.

Resolving whether UTIs caused Ms. Bowling's (presumed) TM is not required. Mr. Bowling's case fails for reasons other than consideration of the urinary tract infections. The issue of urinary tract infections is, therefore, academic. If an analysis concluded that the urinary tract infection did not cause Ms. Bowling's (presumed) transverse myelitis, then this finding would not meaningfully assist Mr. Bowling as "a simplistic elimination of other potential causes" does not suffice "without more, to meet the burden of showing actual causation." Moberly, 592 F.3d at 1323. Conversely, if an analysis concluded that the urinary tract infection did cause Ms. Bowling's (presumed) transverse myelitis, then this finding would prevent any compensation to Mr. Bowling. Accordingly, any discussion of a potential alternative cause is not necessary to this decision.

V. A Hearing Is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Mr. Bowling has had a fair and full opportunity to present his case. After Dr. Souayah presented his initial opinion, Doctors McClain and Donofrio critiqued it, disagreeing with a diagnosis of transverse myelitis. Throughout the pendency of the case, Mr. Bowling was provided multiple opportunities to present expert reports to show that the flu vaccination caused Ms. Bowling's TM. Mr. Bowling submitted supplemental expert reports from Dr. Souayah and Dr. Laughlin. However, even assuming for the sake of argument that the transverse myelitis diagnosis has reliable and substantive medical support, the underlying claim that the flu vaccine could cause Ms. Bowling's TM has itself not been reliably established. The medical theories, proposed by Dr. Souayah, were not persuasive enough to link Ms. Bowling's TM to the flu vaccine. Therefore, a hearing is not needed to resolve these issues.

VI. Conclusion

Mr. Bowling warrants sympathy for watching Ms. Bowling suffer in her final days and witnessing her death. However, the requirements of the Vaccine Act must be satisfied before compensation can be awarded. Here, Mr. Bowling has not presented sufficient evidence to show that the flu vaccine caused Ms. Bowling's TM. Accordingly, his claim for compensation is DENIED.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, which are available on the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master